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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRIAN HAAB, PATRICK BROWN and TIDHAR SHALON

Appeal 2008-0012
Application 09/550,303
Technology Center 1600

Decided: August 10, 2009

Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES, GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a polypeptide microarray. The Examiner has rejected the claims as anticipated by or obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part.

STATEMENT OF THE CASE

The Specification discloses "a substrate with a surface having a microarray of at least 10^3 distinct polynucleotide or polypeptide biopolymers in a surface area of less than about 1 cm^2" (Spec. 3: 26-28). "The substrate includes, in one aspect, a glass support, a coating of a polycationic polymer, such as polylysine . . . , and an array of distinct biopolymers electrostatically bound non-covalently to said coating, wherein each distinct biopolymer is disposed at a separate, defined position" (*id.* at 4: 2-6).

Claims 10, 13-16, 18, 31, and 33-37 are pending and on appeal. Claims 10, 31, and 36 are representative and read as follows:

10. A microarray of discrete polypeptides on a slide, wherein each polypeptide is of at least 50 amino acids in length, wherein said microarray comprises 1000 or more discrete regions of distinct polypeptide per cm^2 of slide wherein discrete regions have a diameter of from 20 to 200 μm, produced by the method of:

(a) loading an aqueous solution of a selected polypeptide of at least 50 amino acids in length in a reagent-dispensing device having an elongate capillary channel adapted to hold a quantity of the reagent solution and having a tip region at which the solution in the channel forms a meniscus,

(b) tapping the tip of the dispensing device against a surface of a planar solid support at a defined position, with an impulse effective to break the meniscus in the capillary channel and deposit a selected volume between 0.002 and 2 nl of solution of the surface of the planar solid support, and

(c) repeating steps (a) and (b) until said microarray is formed.

31. A microarray of discrete polypeptides on a slide, wherein each polypeptide is of at least 50 amino acids in length and wherein said microarray comprises 1000 or more discrete regions of distinct polypeptide per cm^2 of slide, and wherein discrete regions have a diameter of from 20 to 200 μm.

36. The microarray of polypeptides according to Claim 31, wherein said slide comprises a cationic film which binds said polypeptide.

The claims stand rejected as follows:

• Claims 31 and 33-35 under 35 U.S.C. § 102(e) as anticipated by Winkler[1] (Ans. 3);

• Claims 10, 13-15, 18, 31, 33-35, and 37 under 35 U.S.C. § 102(e) as anticipated by Barrett[2] (Ans. 5);

• Claims 16 and 36 under 35 U.S.C. § 103(a) as obvious in view of Barrett and Van Ness[3] (Ans. 13);

• Claims 10, 13-15, 18, 31, and 33-35 under 35 U.S.C. § 103(a) as obvious in view of Beattie,[4] Zubay,[5] and Chang[6] (Ans. 6); and

• Claims 16 and 36 under 35 U.S.C. § 103(a) as obvious in view of Beattie, Zubay, Chang, and Van Ness (Ans. 12).

ANTICIPATION: WINKLER

Issue

The Examiner finds that Winkler discloses a product meeting all of the limitations of claims 31 and 33-35 (Ans. 3).

Appellants contend that Winkler describes "methods of synthesizing polymers *in situ* on a substrate" (Appeal Br. 5). Appellants cite Fodor[7] as

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[1] Winkler et al., US 5,677,195, Oct. 14, 1997
[2] Barrett et al., US 5,252,743, Oct. 12, 1993
[3] Van Ness et al. US 5,667,976 Sept. 16, 1997
[4] Beattie, US 5,843,767, Dec. 1, 1998
[5] Geoffrey Zubay, *Biochemistry* 3rd ed., 964-966, (1993)
[6] Chang, US 4,829,010, May 9, 1989
[7] Fodor et al., 251 *Science* 767-773 (1991).

evidence that *in situ* synthesis provides coupling yields of 85-95% per cycle, and calculate that synthesis of a polypeptide 50 amino acids long would result in only 0.5% of the synthesized polypeptide having the desired sequence (Appeal Br. 9). Appellants conclude that "synthesis of a 50-mer using [Winkler's] method will result in a heterogeneous mixture of polypeptides, only 5 molecules in a 1000 of which will have the correct sequence" (*id.*).

The Examiner does not dispute Appellants' calculations regarding *in situ* synthesis, but contends that "[t]he claims merely require polypeptides of at least 50 amino acids positioned in discrete regions. The claims do not define the composition of the polypeptides on the microarray or within any give[n] region." (Ans. 4.)

The issue with respect to this rejection is: Did the Examiner err in concluding that claim 31 reads on the product disclosed by Winkler?

Findings of Fact

1. Winkler discloses "[m]ethods and devices for synthesizing high-density arrays of diverse polymer sequences such as diverse peptides" (Winkler, col. 2, ll. 15-16).

2. Winkler discloses that "the process may be readily adapted to form polymers having 3, 4, 5, . . . 50, 75, 100 or more monomers therein" (*id.* at col. 17, ll. 55-57).

3. Winkler discloses that "[i]n preferred embodiments, there are at least about 1000 reaction regions per cm^2 of substrate" (*id.* at col. 18, ll. 48-49).

4. Claim 31 is directed to a product that comprises "discrete regions of distinct polypeptide" (claim 31).

5. The Specification states that it provides "[m]ethods and compositions . . . for forming a microarray of polypeptide regions on a solid support, where each region in the array has a known amount of a selected polypeptide" (Spec. 4: 25-27).

6. The Specification states that "'*[d]istinct biopolymers*', as applied to the biopolymers forming a microarray, means an array member which is distinct from other array members on the basis of a different biopolymer sequence, and/or different concentrations of the same or distinct biopolymers, and/or different mixtures of distinct or different-concentration biopolymers" (*id.* at 7: 12-16).

7. The Specification states that "[t]hus, an array of 'distinct polynucleotides' means an array containing, as its members, (i) distinct polynucleotides, which may have a defined amount in each member, (ii) different, graded concentrations of given-sequence polynucleotides, and/or (iii) different-composition mixtures of two or more distinct polynucleotides." (*Id.* at 7: 17-20.)

8. The Specification describes "embodiments of a substrate having a microarray of biological polymers carried on the substrate surface, in particular a microarray of distinct polypeptides" (*id.* at 15: 8-10).

9. The Specification describes making the microarray embodiments by depositing "defined volumes of distinct biopolymers" on a derivatized glass slide (*id.* at 16: 21-22).

10. The Specification states that "in a preferred embodiment, the biopolymers have lengths of at least about 50 units, *e.g.*, amino acids, nucleotides, *etc*., i.e., substantially longer than polymers which can be formed in high-density arrays by various *in situ* synthesis schemes" (*id.* at 17: 5-8).

11. The Specification states that the "polypeptide biopolymers may comprise polypeptides from any source. . . . Usually the polypeptides on each discrete region of the array will be substantially pure." (*Id.* at 17: 9-17.)

Principles of Law

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Analysis

The Examiner does not dispute Appellants' assertion that using Winkler's method to make a product having a 50-amino acid polypeptide immobilized on a substrate would result in only 0.5% of the desired polypeptide in the synthesized product; the remaining 99.5% of the polypeptide in a given region would be a mixture of polypeptides having different lengths and sequences. The Examiner, however, interprets claim 31 to read on such a product because the claim does not define the composition of polypeptide in a given region (Ans. 4).

In our view, the Examiner's interpretation of claim 31 is broader than is reasonable when the claim is read in light of the Specification. The Specification discloses a method of making polypeptide microarrays that begins with intact polypeptides, which are then deposited onto a substrate. The Specification also expressly distinguishes the disclosed microarrays from those that are made by *in situ* synthesis, like those of Winkler.

When the claims are read in light of the Specification's definition of "distinct biopolymers" and the description of the disclosed embodiments, therefore, a person of ordinary skill in the art would understand claim 31's reference to "distinct polypeptides" to mean either a substantially pure polypeptide, or a *defined* mixture of specific polypeptides. A skilled worker would not interpret a "distinct polypeptide" to encompass the undefined mixtures of polypeptides that would result from using Winkler's method to synthesize a 50-amino acid polypeptide *in situ*.

Conclusion of Law

The Examiner erred in concluding that claim 31 reads on the product disclosed by Winkler.

ANTICIPATION: BARRETT

Issue

The Examiner has rejected claims 10, 13-15, 18, 31, 33-35, and 37 under 35 U.S.C. § 102(e) as anticipated by Barrett (Ans. 5). The Examiner finds that Barrett discloses "a microarray of discrete polypeptides on a slide (Column 8, lines 15-20) wherein each polypeptide is at least 50 amino acids (e.g. antibody, Abstract), wherein the microarray comprises 1000 or more

discrete regions of polypeptide/cm^2 wherein the regions have a diameter o[f] 20 to 200 μm" (Ans. 5).

Appellants contend that Barrett does not disclose all the elements of the claimed invention because it "fail[s] to teach a cationic film on a solid support capable of binding peptide, as claimed in the present invention" (Appeal Br. 12).

The issue with respect to this rejection is: Have Appellants shown that the Examiner erred in finding that Barrett discloses the product of claim 31?

Additional Findings of Fact

12. Barrett discloses "methods for forming predefined regions on a surface of a solid support, wherein the predefined regions are capable of immobilizing anti-ligands" (Barrett, col. 5, ll. 14-17).

13. Barrett discloses that the "substrate may be . . . slides" (*id.* at col. 8, ll. 15-19).

14. Barrett discloses that "examples of anti-ligands that can be investigated by this invention include . . . immunoglobulins, e.g., monoclonal and polyclonal antibodies" (*id.* at col. 20, ll. 52-60).

15. Barrett discloses that its methods "make use of caged binding members attached to the surface to enable selective activation of the predefined regions. The caged binding members are converted to binding members ultimately capable of binding anti-ligands upon selective activation of the predefined regions." (*Id.* at col. 5, ll. 17-22.)

16. Barrett discloses that "selected regions of the surface may be irradiated to provide activated binding members" (*id.* at col. 18, ll. 57-58).

17. Barrett discloses that "[i]n preferred embodiments, the exposed area is less than about 10,000 μm^2 or, more preferably, less than about 100 μm^2. Spaces between activated regions are not critical and will generally be greater than about 1 μm." (*Id.* at col. 18, l. 68 to col. 19, l. 4.)

Principles of Law

"[I]n an *ex parte* proceeding to obtain a patent, . . . the Patent Office has the initial burden of coming forward with some sort of evidence tending to disprove novelty." *In re Wilder*, 429 F.2d 447, 450 (CCPA 1970).

"[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

"Any arguments or authorities not included in the brief or a reply brief . . . will be refused consideration by the Board, unless good cause is shown." 37 C.F.R. § 41.37(c)(1)(vii).

Analysis

Barrett discloses microarrays, on slides, of polypeptides including antibodies. As evidenced by Zubay (see FF 31, infra), antibodies are at least 50 amino acids in length. Barrett does not expressly disclose 1000 discrete regions of polypeptides per cm^2 or discrete regions with a diameter of 20-200 μm, but it describes a preferred embodiment with regions having an area of 10,000 μm^2. A circular region with an area of 10,000 μm^2 would have a diameter of about 113 μm.[8] Since a square centimeter is 10,000 μm long on

[8] The area of a circle is given by the formula Area = π x (radius)^2, or

each side, this embodiment also reasonably appears to describe a microarray with at least 1000 regions per square centimeter.

We find that Barrett discloses a microarray meeting all the limitations of claim 31.

The only argument Appellants rely on in contesting this rejection is that Barrett does not teach a cationic film on the solid support (Appeal Br. 12). As the Examiner pointed out, however, a cationic film is only a limitation of claims 16 and 36, which were not rejected as anticipated by Barrett.

Conclusion of Law

Appellants have not shown that the Examiner erred in finding that Barrett discloses the product of claim 31. Claims 10, 13-15, 18, 33-35, and 37 fall with claim 31 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS: BARRETT AND VAN NESS

Issue

The Examiner has rejected claims 16 and 36 under 35 U.S.C. § 103(a) as obvious in view of Barrett and Van Ness (Ans. 13). The Examiner acknowledges that Barrett does not teach a cationic film on the solid support, but finds that "cationic films on solid supports for binding polypeptides were well known in the art . . . as taught by Van Ness et al. who specifically teach the cationic film provides for convenient attachment of the polypeptide" (*id.*

Area = π x (diameter/2)^2. A circle with a diameter of 113 μm therefore has an area of π x (113/2)^2 = 10,029 μm^2.

at 14). The Examiner concludes that it would have been obvious to modify Barrett's device by providing a cationic film on a solid support (*id.*).

Appellants contend that Barrett teaches that its method is superior to nonspecific attachment like that provided by a cationic film, because Barrett's method allows specifically addressable and modulatable levels of attachment, and therefore a skilled worker would not have considered it obvious to modify it to include a cationic film (Appeal Br. 20-21).

The issue with respect to this rejection is: Have Appellants shown that the Examiner erred in concluding that a person of ordinary skill in the art would have considered it obvious to modify Barrett's product by immobilizing polypeptides using a cationic film?

Additional Findings of Fact

18. Van Ness discloses "compositions comprising an activated oligonucleotide, which can be covalently attached to a polymer-coated support such as a bead" (Van Ness, col. 2, ll. 18-20).

19. Van Ness discloses that the solid support can be coated with a polymer having an amine functionality (*id.* at col. 6, ll. 14).

20. Van Ness discloses that the "polymer-coated solid supports are then conjugated with activated oligonucleotides or other substances of interest. . . . [A]n amine-containing polymer can be covalently linked through the amine to a protein. . . . Conveniently, the polymer is coupled to a solid support, such as a bead." (*Id.* at col. 6, ll. 20-28.)

Principles of Law

An invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . .[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

"[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 420.

However, "[w]e must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

Analysis

Barrett discloses a method of immobilizing anti-ligands in which a solid support is coated with inactive (caged) binding members which are selectively activated in predefined regions by, e.g., irradiation. (FFs 15, 16.) Barrett discloses that the irradiated areas are preferably less than 10,000 μm^2 (FF 17), which corresponds to a square 100 μm on a side or a circle with a diameter of 113 μm.

Van Ness discloses immobilizing proteins, among other things, on beads coated with a polymer that can have an amine functionality (FF 20). The Examiner concludes that it would have been obvious to modify Barrett's

device by immobilizing proteins using the cationic film disclosed by Van Ness because Van Ness teaches that its film allows convenient attachment (Ans. 14).

Appellants argue that Barrett teaches that its method has the advantage of allowing reagents to be attached in specific, selectively activated regions of a substrate, and that Barrett teaches avoiding methods of nonspecific attachment like that of Van Ness (Appeal Br. 20). Appellants conclude that it would not have been obvious to incorporate a method of attachment using a cationic film coating in Barrett's apparatus because that would render inoperative Barrett's selectively photoactivatable coating (*id.*).

We agree with Appellants that the Examiner has not adequately shown that a skilled worker would have considered it obvious to modify Barrett's device by immobilizing the anti-ligands using Van Ness' cationic film rather than Barrett's activated binding members. Barrett's focus is on making small regions capable of binding anti-ligand, while leaving the binding members on the rest of its substrate inactive. The Examiner has pointed to nothing in Van Ness that would support a finding that Van Ness' method of immobilizing a protein would be capable of providing the same capacity to activate only certain areas of a substrate for immobilizing a particular anti-ligand.

The fact that other methods of immobilizing compounds on a substrate were known, without more, does not mean that any known method if immobilization would be suitable for Barrett's apparatus. The evidence of record does not support a conclusion that a skilled worker would consider

Van Ness' method of immobilization to be interchangeable with Barrett's method.

Conclusion of Law

Appellants have shown that the Examiner erred in concluding that a person of ordinary skill in the art would have considered it obvious to modify Barrett's product by immobilizing polypeptides using a cationic film.

OBVIOUSNESS: BEATTIE, ZUBAY, AND CHANG

Issue

The Examiner has rejected claims 10, 13-15, 18, 31, and 33-35 under 35 U.S.C. § 103(a) as obvious in view of Beattie, Zubay, and Chang (Ans. 6). The Examiner finds that Beattie teaches a microarray meeting most of the limitations but does not "specifically teach polypeptides arrayed on a slide" (*id.* at 7), Chang teaches an array of antibodies on a slide (*id.*), and Zubay teaches that antibodies are at least 50 amino acids long (*id.* at 6). The Examiner concludes that it would have been obvious to "apply the slide of Chang to the broadly defined substrate of Beattie et al to thereby provide a light-transparent support . . . for the obvious benefit of permitting detection and analysis of reactions on the support" (*id.* at 7).

Appellants contend that it would not have been obvious to deposit Beattie's binding reagents on a slide because Beattie "specifically teach[es] that a flat surface design is undesirable" (Appeal Br. 14) and "absolutely requires the presence of channels through the substrate . . . in order to function" (*id.* at 16).

The issue with respect to this rejection is: Have Appellants shown that the Examiner erred in concluding that it would have been obvious to modify Beattie's product by using Chang's slide to immobilize the binding reagents in Beattie's product?

Additional Findings of Fact

21. Beattie discloses that "[g]enosensors, or miniaturized 'DNA chips' are currently being developed . . . for hybridization analysis of DNA samples. DNA chips typically employ arrays of DNA probes tethered to flat surfaces." (Beattie, col. 2, l. 66 to col. 3, l. 2.)

22. Beattie discloses that prior art chips have the disadvantage that "a flat surface design introduces a rate-limiting step in the hybridization reaction, i.e., diffusion of target molecules over relatively long distances before encountering the complementary probes on the surface" (*id.* at col. 3, ll. 19-22).

23. Beattie discloses "a novel flow-through genosensor, in which nucleic acid recognition elements are immobilized within densely packed pores or channels, arranged in patches across a wafer of solid support material" (*id.* at col. 1, ll. 29-32).

24. Beattie discloses that its device "is designed to overcome the inherent limitations in current solid phase hybridization materials, eliminating the diffusion-limited step in flat surface hybridizations" (*id.* at col. 3, ll. 23-26).

25. Beattie discloses that its device uses nanochannel glass (NCG) wafers "as high surface area nanoporous support structures to tether DNA targets or probes for hybridization" (*id.* at col. 9, ll. 44-49).

26. Beattie discloses that "nanochannel glass structure can possess packing densities in excess of $3x10^{10}$ channels per square centimeter. . . . A variety of materials can be immobilized or fixed to the glass surfaces within the channels of the NCG array." (*Id.* at col. 9, ll. 54-58.)

27. Beattie discloses that the NCG wafer is "bonded on the upper side to a polymeric layer containing an array of orifices which align with the array of nanochannel bundles and serve as sample wells" (*id.* at col. 10, ll. 37-39).

28. Beattie teaches that the development of the polymeric array involves, among other steps, "lamination tooling and process development" (*id.* at col. 10, ll. 54-55).

29. Beattie discloses that "[i]nitial lamination process development is carried out using unablated polymeric material (or alternatively, using glass slides and/or silicon wafers)" (*id.* at col. 11, ll. 40-42).

30. Beattie discloses that porous silicon wafers can also be used to immobilize the binding reagents in its device (*id.* at col. 11, ll. 56-64).

31. Zubay discloses that antibodies are more than 50 amino acids long (Zubay 965, legend to Figure 33.2).

32. Chang discloses an "immunoassay device . . . compris[ing] a support which has a substantially planar surface. On the support is an array of small, closely-spaced, discrete, antibody coated areas. A cover is spaced from the support surface and is positioned over the array of antibody coated areas." (Chang, col. 1, ll. 55-60.)

33. Chang discloses that "[p]referably, the support and the cover are light transparent. The support surface may be glass or plastic microscope slides." (*Id.* at col. 2, ll. 7-9.)

Analysis

Beattie teaches a device in which a binding reagent is immobilized in the pores of a nanochannel glass or porous silicon wafer. The Examiner concludes that it would have been obvious to use Chang's glass slide for the substrate in Beattie's device in order to provide a light-transparent support (Ans. 7). The Examiner reasons that "because Beattie and Chang teach the structural element of the microarray as claimed, the process of making the microarray as recited in [claim 10] does not distinguish the microarray over that of prior art" (*id.* at 9).

Appellants argue that it would not have been obvious to substitute a glass slide for Beattie's channel-containing substrate because Beattie teaches that a flat surface design is undesirable (Appeal Br. 14) and Beattie's device requires channels through the substrate in order to function (*id.* at 16).

We agree with Appellants that the Examiner has not adequately explained why it would have been obvious to use Chang's glass microscope slide to immobilize the binding reagent in Beattie's device. Beattie refers to glass slides only in the context of developing the lamination process for attaching a supporting polymeric layer to the nanochannel glass (NCG) layer to which the binding reagents are immobilized. Beattie does not suggest a planar, non-channeled glass layer for immobilizing its binding reagents.

Beattie's entire disclosure, in fact, focuses on the benefits of immobilizing binding reagents within the pores of a nanoporous support –

either NCG or porous silicon. Beattie expressly discusses the advantages of its approach over prior art approaches, like that of Chang, where the binding reagent is immobilized on the surface of a planar support. A skilled worker, reading Beattie and Chang, therefore would understand that substituting a planar support for Beattie's nanoporous support would create a product having the disadvantage discussed by Beattie; specifically, it would require diffusion of target molecules over relatively long distances, creating a rate-limiting step in binding reactions.

The only offsetting advantage identified by the Examiner of using Chang's glass slide in Beattie's device is that a glass slide would be light transparent. But the Examiner has not identified any reason why light transparency would be desirable in Beattie's device, nor has she provided any evidence that the NCG or porous silicon used by Beattie are not themselves light transparent. The Examiner therefore has not provided sufficient evidence or reasoning to support a conclusion that a skilled worker would have considered it obvious to use a glass slide to immobilize the binding reagents in Beattie's device.

The Examiner also rejected claims 16 and 36 as obvious in view of Beattie, Zubay, Chang, and Van Ness (Ans. 12). The Examiner, however, has not pointed to any disclosure in Van Ness that would make up for the deficiency discussed above. The rejection based on Beattie, Zubay, Chang, and Van Ness is reversed as well.

Conclusion of Law

Appellants have shown that the Examiner erred in concluding that it would have been obvious to modify Beattie's product by using Chang's slide to immobilize the binding reagents in Beattie's product.

SUMMARY

We affirm the rejection of claims 10, 13-15, 18, 31, 33-35, and 37 as anticipated by Barrett. We reverse the other rejections on appeal.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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